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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,063	05/24/2000	John D. Sharp	MBIO99-030CP1M	5645

7590 07/14/2003
INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS, INC.
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CAMBRIDGE, MA 02139

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/14/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,063

Applicant(s)

MCCARTHY ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 24-26, 28-30, 33-36 and 38-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 24-26, 28-30, 33-36, 38-43 and 45-47 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED OFFICE ACTION

Applicant's amendment in paper No. 18, filed on 13 May 2003 is acknowledged and entered. Following the amendment, claims 8 and 30 are amended.

Currently, claims 8-10, 24-26, 28-30, 33-36 and 38-47 are pending, and under consideration.

Withdrawal of Objections and Rejections:

The prior art rejection of claims 8, 10, 28, 47, 30 under 35 U.S.C. 102(a) as being anticipated by Blanchard et al., US 5,807,726, is withdrawn in view of applicant's amendment.

The prior art rejection of claims 8, 10, 28, 47, 30 under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84), is withdrawn in view of applicant's amendment.

The prior art rejection of claims 33 and 34 under 35 U.S.C. 102(a) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blanchard et al., US 5,807,726, or over Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84), is withdrawn in view of applicant's amendment.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 30 and the dependent claims 10, 28, 47, 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly amended claims 8 and 30 recite "over the length of said nucleic acid molecule". Applicants have not pointed out, nor can the Examiner locate, the basis for such a limitation in the specification.

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This is a new matter rejection.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10, 24-26, 28-30, 33-36 and 38-41 and 47 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the last Office Action, paper No. 17, mailed on 13 February 2003, at page 3, and for the reasons below.

Applicants argument, filed on 13 May 2003 (paper No. 18) has been fully considered, but is not deemed persuasive for reasons below.

At page 3 of the response, the applicant argues that a definition of "a TANGO 294 activity" is provided in the specification, at pages 5 and 8, and a person of ordinary skill in the art could very easily determine what is meant by "a TANGO 294 activity" in the present claims. This argument is not persuasive because, as pointed out by applicants, the specification states that an activity, ... refers to an activity exerted by a protein or polypeptide of the invention on a responsive cell ... according to standard techniques (page 5), and that TANGO 294 protein is involved in facilitating absorption and metabolism of fat (page 8), neither of which defines any specific activity of TANGO 294. It is noted that the specification indicates, at page 6, that such activities can be a direct or an indirect activity, such as formation of protein-protein interaction ..., binding with a ligand or an intracellular target, modulation of cellular proliferation, differentiation, of chemotaxis, of cellular migration, and of cell death (page 6, the first paragraph). As such, it is unclear whether TANGO294 may also possess those activities, and the metes and bounds of the claims cannot be determined. "Lipase activity" is suggested.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 24-26, 29, 42, 43 and 45 remain rejected under 35 U.S.C. 112, first paragraph, as the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for the reasons set forth in the last Office Action, paper No. 17, mailed on 13 February 2003, at page 3, and for the reasons below.

Applicants argument in paper No. 18 has been fully considered, but is not deemed persuasive for reasons below.

At page 4 of the response, the applicant argues that TANGO 294 is a lipase, and generating functional variants or fragments is routine in the art, and that the present claims all possess a functional limitation, and the specification indeed enables one of ordinary skill in the art to make the invention commensurate with the scope of the claims. At page 5 of the response, the applicant further argues that TAGO294 contains a lipase serine active site from residues 180-189, and persons of ordinary skill in the art can easily determine which fragments and variants, regardless of their size, possess a TANGO294 (lipase) activity by routine assays. These arguments are not persuasive because, once again, the issue is not whether generating functional variants or fragments or lipase activity assays are routine in the art, nor whether the present TAGO294 contains a lipase serine active site. Rather, the issue is that the present TANGO 294 is an enzyme (a lipase), and has 390 amino acids in its mature form, and that the art has not established nor reasonably predictable that a small fragment such as 40 amino acids of an enzyme molecule of 390 amino acids would retain the desired enzymatic activity even if such a small fragment is from the region contains a lipase serine active site. The specification provides neither guidance nor any working example regarding such functional fragments. Therefore, it is unpredictable such a small fragment would possess the biological property, thus undue experimentation would be required prior to using the claimed invention.

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Claims 28, 47, 33, 38 and 46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, for the reasons set forth in the last Office Action, paper No. 17, mailed on 13 February 2003, at page 4.

Applicants argument in paper No. 18 has been fully considered, but is not deemed persuasive for reasons below.

At page 6 of the response, the applicant argues that, as taught by the prior art, before dietary fats can be taken up and used by the body, they must first be broken down into their component parts by a variety of digestive enzymes, and that determining lipase activity of the TANGO 294 of the present invention is tantamount to determining the absorption or transport activity of the same. This argument is not persuasive because, while digestion of fats requires a lipase, transport and absorption of a lipid is not known to be functional activities of a lipase. By digesting fats and breaking down fats into their component parts, a lipase *facilitates* transport and absorption, but *not modulate* transport and absorption of a lipid, as the art has not established a direct role of a lipase in transport and absorption of a lipid, nor that determining lipase activity of a protein is tantamount to determining the absorption or transport activity of the same.

Claim 8 remains further rejected under 35 U.S.C. 112, first paragraph, as it is not in compliance with the deposit rule for the reason addressed in the last Office Action, paper No. 17, page 5. Applicants statement with this respect filed in paper No. 18 is noted, however, it is not sufficient to overcome the rejection because the statement is not signed.

Conclusion:

No claim is allowed.

Claim 44 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

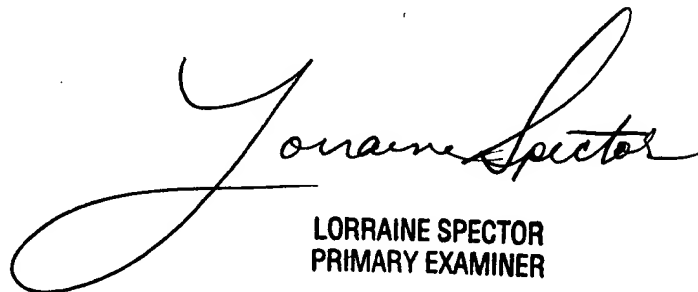
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/8/03


**LORRAINE SPECTOR
PRIMARY EXAMINER**